

PERSPECTIVES AND PRACTICE IN ANTIRETROVIRAL TREATMENT

SAVING MOTHERS, SAVING FAMILIES : THE MTCT-PLUS INITIATIVE

CASE STUDY



World Health Organization



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PERSPECTIVES AND PRACTICE IN ANTIRETROVIRAL TREATMENT

SAVING MOTHERS, SAVING FAMILIES : THE MTCT-PLUS INITIATIVE

CASE STUDY

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About this series

With 42 million people now living with HIV/AIDS, expanding access to antiretroviral treatment for those who urgently need it is one of the most pressing challenges in international health. Providing treatment is essential to alleviate suffering and to mitigate the devastating impact of the epidemic. It also presents unprecedented opportunities for a more effective response by involving people living with HIV/AIDS, their families and communities in care and will strengthen HIV prevention by increasing awareness, creating a demand for testing and counselling and reducing stigma and discrimination.

The challenges are great. Sustainable financing is essential. Drug procurement and regulatory mechanisms must be established. Health care workers must be trained, infrastructure improved, communities educated and diverse stakeholders mobilized to play their part. This series, *Perspectives and Practice in Antiretroviral Treatment*, provides examples of how such challenges are being overcome in the growing number of developing countries in which antiretroviral treatment programmes are underway. The case studies and analyses in this series show how governments, civil society organizations, private corporations and others are successfully providing antiretroviral treatment and care to people with HIV/AIDS, even in the most resource-constrained settings. In documenting these pioneering programmes, WHO hopes that their experiences will both inform and inspire everyone who is working to make access to treatment a reality.

Background

The MTCT-Plus Initiative was conceived in 2001 as a response to the five-point Call to Action on HIV/AIDS issued by Kofi Annan, United Nations Secretary-General. Designed to increase access to HIV/AIDS care and treatment in resource-limited settings, the Initiative built on the dramatic changes that had taken place in the preceding year. Burgeoning political support for HIV/AIDS treatment following the XIII International AIDS conference in Durban, South Africa in 2000 had culminated in the United Nations General Assembly Special Session on HIV/AIDS in 2001. The prices of antiretroviral drugs had dropped by an order of magnitude, and the creation of the Global Fund for AIDS, Tuberculosis and Malaria had dramatically increased the financial resources available for treatment programmes.

In this context, the Rockefeller Foundation convened an international group of scientists, clinicians, policy-makers and patient advocates to design an HIV/AIDS care programme for resource-limited settings. Five working groups incorporated experts from multilateral organizations, local and country-level initiatives, programmes for the prevention of the mother-to-child transmission of HIV, and researchers conducting clinical trials. The working groups also included advocates of the people needing treatment and care, experts in procuring medications and supplies, clinical researchers, ethicists and policy-makers.

Attention focused on the antenatal care setting from the first days of the planning process. The rapid and successful expansion of programmes for the prevention of the mother-to-child transmission of HIV over the preceding years provided a model and an opportunity. These programmes illustrated the effective use of antenatal care as an entry point to care; they had also generated a cohort of HIV-infected mothers without access to treatment. Providing care and treatment to HIV-infected women identified through programmes for the prevention of the mother-to-child transmission of HIV would enable MTCT-Plus to link a treatment initiative to a prevention programme, to further reduce vertical transmission of HIV and to strengthen families and communities as well as individuals.

By winter 2001, the outlines of the MTCT-Plus Initiative had developed and the decision was made to locate MTCT-Plus at Columbia University's Mailman School of Public Health under the leadership of Allan Rosenfield and Wafa

M. El-Sadr. Eight private foundations¹ pledged support, and the Initiative was launched in December 2001 at a ceremony at Kofi Annan's residence in New York City. By summer 2002, 12 demonstration sites in Africa and Asia had been chosen; the first participant was enrolled in February 2003, and an estimated 10 000 people will be enrolled in the program.

OBJECTIVES

The primary objective of the MTCT-Plus Initiative is to provide lifelong care and treatment for HIV/AIDS to families in resource-limited settings. In addition to reducing mortality and morbidity, the Initiative hopes to further reduce the mother-to-child-transmission of HIV; to promote voluntary counselling and testing and other preventive strategies; to strengthen local health care capacity; to decrease stigma among, enhance support for and empower people living with HIV/AIDS; and to develop a model for HIV care in resource-limited settings that can be generalized.

An international review committee selected the initial sites after a request for applications was widely distributed in early 2002. Of the 47 eligible applicants – all of whom had ongoing programmes to prevent the mother-to-child-transmission of HIV, HIV prevalence of at least 5% and the ability to enrol at least 250 people per year – the committee selected 12 demonstration sites. An additional 13 sites were given planning grants.

¹ Bill & Melinda Gates Foundation, William and Flora Hewlett Foundation, Robert Wood Johnson Foundation, Henry J. Kaiser Family Foundation, John D. and Catherine T. MacArthur Foundation, David and Lucile Packard Foundation, Rockefeller Foundation, Starr Foundation and United Nations Foundation.

The 2002 demonstration sites include (Fig. 1):

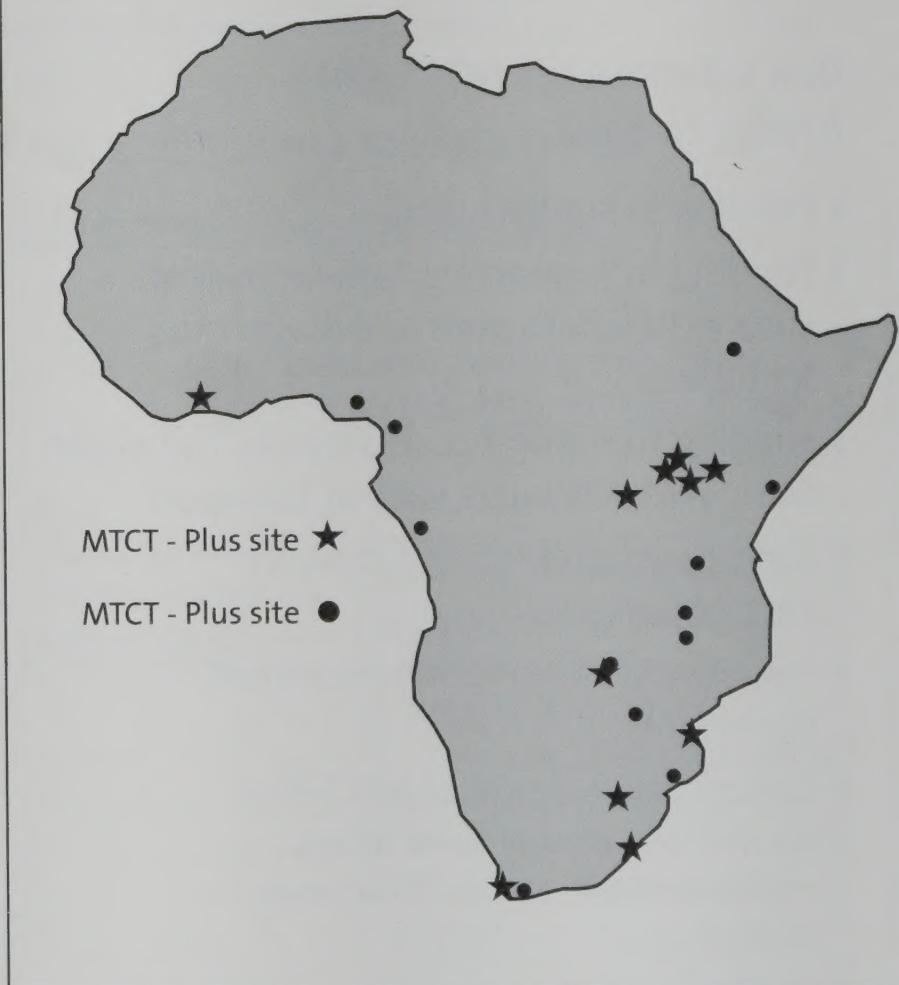
- FSU (Formation Sanitaire Urbaine) de Yopougon-Attié, Abidjan, Côte d'Ivoire;
- Nyanza Provincial General Hospital, Kisumu, Kenya;
- Moi Hospital/Mosoriot Rural Health Center, Eldoret, Kenya;
- Beira Day Hospital, Beira, Mozambique;
- Treatment and Research AIDS Center, Kigali, Rwanda;
- Perinatal HIV Research Unit, University of Witwatersrand, Soweto, South Africa;
- Health Clinics, Cape Town, South Africa;
- Cator Manor Clinic, University of Natal, Nelson Mandela School of Medicine, Durban, South Africa;
- Thai Red Cross AIDS Research Centre, Bangkok, Thailand;
- Mulago Hospital, Kampala, Uganda;
- St Francis Hospital, Kampala, Uganda; and
- Chelstone District Health Clinic, Lusaka, Zambia;

Planning grants were awarded to:

- Cameroon Baptist Health Convention Board, Northwest Province, Cameroon;
- Kingasani Maternity Hospital, Kinshasa, Democratic Republic of the Congo;
- Zewditu Hospital, Addis Ababa, Ethiopia;
- National AIDS Control Program, Ministry of Health, Nairobi, Kenya;
- Embangweni Mission Hospital, Mzimba, Malawi;
- The Lighthouse Project, Lilongwe, Malawi;
- Médecins Sans Frontières—Luxembourg/Primeiro de Maio Health Centre, Maputo, Mozambique;
- Homeland Charities and Abia State University, Umuahia, Nigeria;
- Paediatric Infectious Diseases Unit, University of Cape Town, South Africa;

- Ministry of Health & Muhimbili University College of Health Sciences, Dar Es Salaam, Tanzania;
- Department of Paediatrics, University Teaching Hospital, Lusaka, Zambia; and
- AIDS and Tuberculosis Programme, Ministry of Health, Zimbabwe.

**Fig. 1. MTCT-Plus sites in Africa
(site 12 is in Bangkok, Thailand)**



Description of MTCT-Plus

The fundamental elements of the MTCT-Plus Initiative include linking with programmes for the prevention of the mother-to-child-transmission of HIV, family-centred care and the provision of enhanced HIV-specific primary and preventive care (Box 1). This model provides integrated services – clinical care and prevention, nutrition, family planning, counselling and other supportive care – as well as antiretroviral therapy when indicated. Site eligibility for MTCT-Plus required a successful programme for the prevention of the mother-to-child-transmission of HIV to be in place. The Initiative built on these existing programmes by providing support for an «essential package» of care and treatment.

Box 1. Resources MTCT-Plus brings to sites

- Funding to support staff
- Funding to support key laboratory tests, such as CD4 cell count and diagnostics for infants
- Funding to support costs incurred by people living with HIV/AIDS, such as transport
- Funding to enhance site capacity and infrastructure
- The *Clinical Manual*, and treatment algorithms
- Central procurement of MTCT-Plus medicines : antiretroviral drugs, cotrimoxazole, isoniazid, dapsone, multivitamins and others
- Staff training
- Site support
- Data management
- Programme evaluation

The MTCT-Plus essential package defines a set of interventions integral to the care of people living with HIV/AIDS (Box 2). Developed by an international working group of expert clinicians and consistent with WHO recommendations, these guidelines set out a minimum package of care to be provided to all MTCT-Plus participants.

The objectives of care in MTCT-Plus are to maintain and/or restore health to the families of people living with HIV/AIDS. Rather than waiting until a person living with HIV is ill and in an advanced stage of HIV disease, MTCT-Plus aims at engaging people in an HIV care programme at an early stage to maintain their health. Education and counselling, preventing opportunistic infections and early management of complications when they occur are all critically important, as is the use of antiretroviral drugs when indicated.

Box 2. Elements of care in MTCT-Plus

- Health care for adults and children living with HIV/AIDS
- Early diagnosis of infant HIV-infection status
- Clinical and immune monitoring
- Prevention of opportunistic infections
- Antiretroviral therapy
- Education and counselling
- Adherence support
- Social and psychological support
- Outreach and community linkage
- Retention in long-term care
- Prevention of transmission to others

THE CLINICAL MANUAL

With the assistance of an international advisory committee, the MTCT-Plus Clinical Working Group developed detailed and specific treatment algorithms for HIV/AIDS care in resource-limited settings. The *Clinical Manual*, whose first edition was completed in January 2003,² summarized decisions about what to include in the essential package, which infant diagnostic algorithms should be employed, when to start and switch antiretroviral agents in adults and children, which antiretroviral drugs to use, and how to monitor people receiving antiretroviral therapy. In

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addition to outlining MTCT-Plus protocols, the *Clinical Manual* reviews topics such as coordination of family care, adherence, psychosocial and nutritional support, education of people living with HIV/AIDS and community outreach. The manual will be updated several times a year and will be available on the website as a living document.

THE MULTIDISCIPLINARY TEAM

One of the principles of the MTCT-Plus Initiative is that HIV care and treatment should not be provided by physicians alone. Not only do human resource shortages preclude physician-directed care in many countries, but experience in resource-rich settings has demonstrated that care delivered by a multidisciplinary team is simply more effective. To that end, MTCT-Plus teams are composed of physicians, nurses, medical officers, counsellors, social workers, community advocates, outreach workers and peer educators. The team composition varies from site to site, but communication, regular team meetings and interdisciplinary partnership are hallmarks of the MTCT-Plus approach.

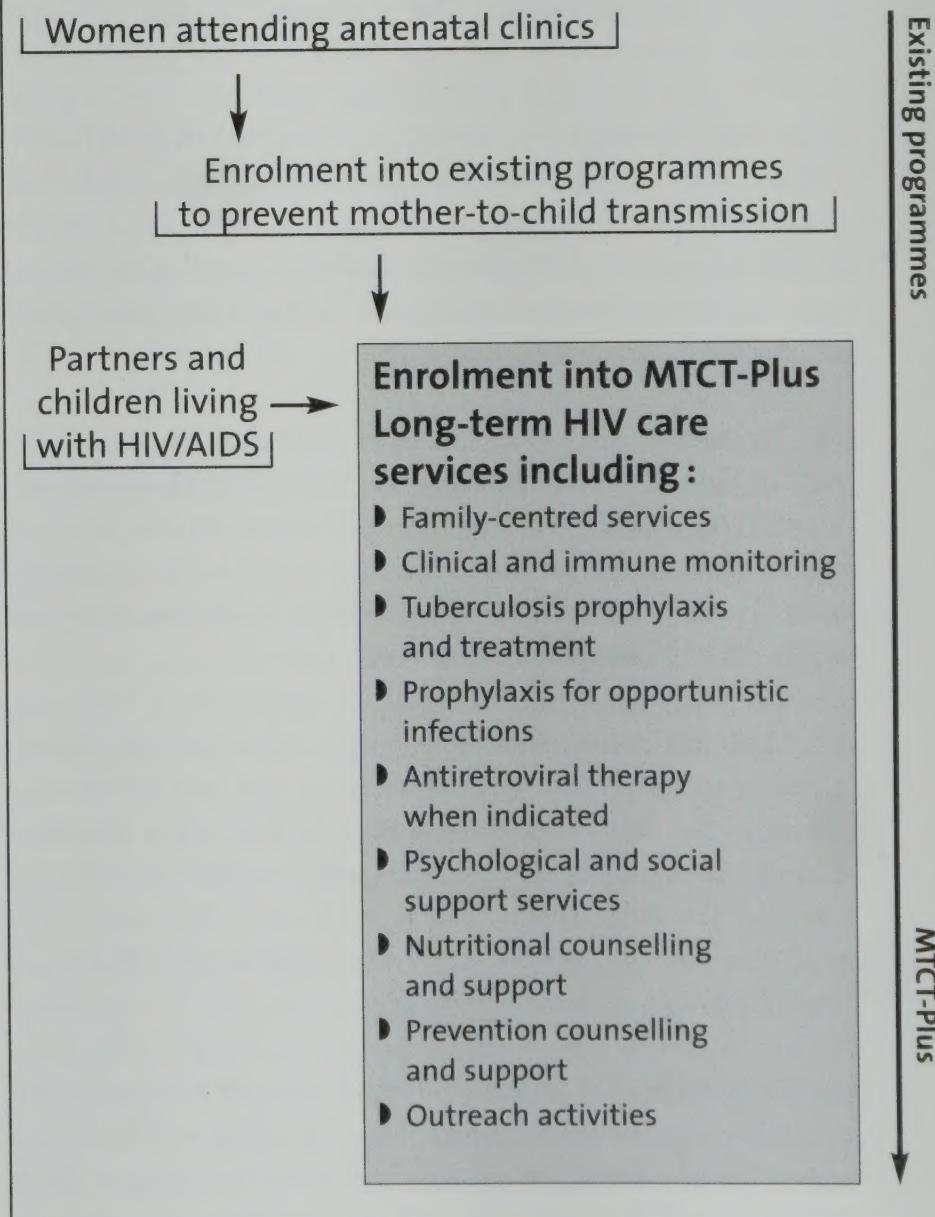
PEOPLE SERVED

MTCT-Plus is designed to provide lifelong care and treatment to women living with HIV/AIDS and families identified through programmes to prevent the mother-to-child transmission of HIV in resource-limited settings. As such, HIV-infected women who are or who have recently been pregnant are the entry point to the care programme. Once enrolled, women may refer their children, partners and other household members. By providing care during pregnancy, MTCT-Plus will further decrease the mother-to-child transmission of HIV. By supporting maternal health, MTCT-Plus will reduce the number of children orphaned. By preventing illness, MTCT-Plus will enable adult family members to continue working to support the household, strengthening individuals, families and communities.

The family focus of MTCT-Plus includes enhanced diagnostic protocols for infants, permitting the early identification and treatment of people infected with HIV/AIDS. The care and treatment of children is an integral part of MTCT-Plus, and detailed protocols have been developed for infants and children.

Women are eligible for MTCT-Plus if they have recently enrolled in a programme for the prevention of the mother-to-child-transmission of HIV (Fig. 2). Most of these index pregnant women living with HIV/AIDS are likely to be healthy, and we estimate that about 20 % will be eligible for antiretroviral therapy at the time of enrolment. However, their partners and children may be at more advanced stages of HIV disease, with a higher proportion of the latter group eligible for antiretroviral therapy at enrolment. Once enrolled in MTCT-Plus, however, people living with HIV/AIDS have joined a programme of life-long care. They receive education and counselling, nutritional and psychosocial support and ongoing clinical and laboratory monitoring. When clinically appropriate, prophylactic and antiretroviral therapies are initiated.

Fig. 2. Eligibility for MTCT-Plus



¹ The *Clinical Manual* is available in English, French, Spanish, Portuguese and Thai: by contact MTCT-Plus at mtctplus@columbia.edu.

Each MTCT-Plus site has developed eligibility criteria for programme enrolment that further refine the algorithm in Fig. 2. These local eligibility criteria are developed with the assistance of community advisory boards and/or ethical review committees and ensure that community values and priorities are taken into consideration. Each site has developed a working definition of a household that will govern the enrolment of family members. The programmatic emphasis on adherence and retention in care has led many sites to restrict participation to people living close to the clinic. Many have asked that participants make a commitment to secondary prevention, and some require participants to have disclosed their HIV status to at least one other person.

CLINICAL CARE

The MTCT-Plus essential package encompasses more than antiretroviral treatment. As outlined in the *Clinical Manual*, participants in the MTCT-Plus programmes receive education and counselling, access to family planning and reproductive health services, nutritional counselling and support including multivitamins, adherence support in the form of pill boxes and medication blister packs, psychosocial support including support groups and peer educator programmes and linkage to community resources.

Prophylaxis of opportunistic infections plays a prominent role in MTCT-Plus, as does the early identification and management of HIV-related complications. Participants are encouraged to return to clinic for evaluation at regular intervals defined by their disease stage, and education and support are available at every visit.

The use of cotrimoxazole is encouraged in all infants exposed to HIV starting at 4 weeks of age and continuing through the first 12 months of life. For older children known to be infected with HIV, cotrimoxazole is recommended for those with $CD4\% < 15$ or ≤ 200 total CD4 cells per mm^3 as well as all children previously diagnosed with *Pneumocystis carinii* infection.

Cotrimoxazole (or dapsone if they cannot tolerate cotrimoxazole) is also recommended for all adults with symptomatic AIDS (WHO stage IV) and everyone with $CD4 \leq 200$ per mm^3 . At some sites, when consistent with country guidelines, cotrimoxazole is prescribed for all adults with $CD4 \leq 500$ per mm^3 .

The MTCT-Plus Initiative pays particular attention to tuberculosis, the most common and deadly opportunistic infection among people living with HIV/AIDS globally. Early identification of tuberculosis is emphasized through regular assessment for related signs and symptoms. In addition, sites are encouraged to maintain strong links with their local tuberculosis control programmes. The use of isoniazid for treating latent tuberculosis infection is encouraged in settings in which active tuberculosis disease can be excluded. In coordination with local tuberculosis programmes, MTCT-Plus sites in high-prevalence areas are variously providing isoniazid for all adult participants without active tuberculosis or to those with positive tuberculin skin tests. The use of isoniazid in infants and children is similarly coordinated with local tuberculosis control programmes and policies.

Additional preventive treatments at some sites include the use of fluconazole to prevent cryptococcal meningitis as well as insecticide-treated bednets and intermittent malaria treatment during pregnancy. MTCT-Plus sites also ensure routine childhood vaccination and provide education about food and water hygiene.

ANTIRETROVIRAL TREATMENT REGIMENS

The clinical and biological criteria MTCT-Plus uses to determine eligibility for antiretroviral therapy are similar to those proposed in WHO guidelines, with additional expanded eligibility for adults with both CD4 cells <350 cells per mm^3 and WHO stage II or III HIV disease. MTCT-Plus uses a standardized treatment approach. Asymptomatic adults, with ≤ 200 CD4 cells per mm^3 , adults with WHO stage II or III HIV disease and ≤ 350 CD4 cells per mm^3 , and all adults with WHO stage IV HIV disease, irrespective of CD4 count are eligible for antiretroviral therapy. Infants (1–12 months with two positive virological HIV tests) are eligible when they present with failure to thrive or AIDS-defining illness (United States Centers for Disease Control category C and WHO stage III HIV disease) or – when asymptomatic – when they have a $CD4\% < 20$. Children are eligible when they present with failure to thrive, AIDS-defining illness, or – even when asymptomatic – with $CD4\% < 15$.

As with eligibility criteria for participation, criteria for eligibility for antiretroviral therapy are defined at the site level. Each site has developed its own protocols, many of which include additional non-biologic criteria such as

evidence of regular clinic attendance, residence within certain distance from the site, results of an evaluation of the home environment and of social support and disclosure.

MTCT-Plus follows the WHO-endorsed public health approach to the use of antiretroviral therapy, using standardized first- and second-line regimens for adults and children (Tables 1, 2). Although MTCT-Plus provides structured algorithms for the use of antiretroviral drugs, MTCT-Plus sites do not use identical regimens. In consultation with the MTCT-Plus Secretariat, sites choose from a limited formulary of antiretroviral agents.

Considerations for the choice of first-line agents include compliance with WHO and country guidelines for the use of antiretroviral drugs. Toxicity and teratogenicity are important concerns, as MTCT-Plus, by definition, includes many pregnant women and women who are likely to become pregnant again. Simple regimens are emphasized, with low pill burden and no refrigeration requirements. Most sites emphasize minimizing interactions with anti-tuberculosis medication; the prevalence of HIV-2 is an issue in some regions. Cost is also considered, and generic drugs are used if WHO has prequalified them and country regulations permit them. Single-drug replacements have been selected in case of toxicity, and a second-line regimen has been identified for clinical or immune failure.

The choice of regimens for children was further complicated by the fact that stavudine suspension, required for smaller infants, must be refrigerated and thus cannot be used at most sites. In addition, efavirenz dosing for younger infants has not yet been firmly established, and the use of abacavir in infants less than 1 year of age has not yet been validated.

Table 1. Examples of MTCT-Plus highly active antiretroviral therapy regimens for adults

| First line | Second line |
|-----------------|-----------------|
| ZDV + 3TC + NVP | ddI + D4T + NFV |
| ZDV + 3TC + ABC | ddI + D4T + NFV |
| D4T + 3TC + NVP | ZDV + ddI + NFV |

Table 2. Examples of MTCT-Plus highly active antiretroviral therapy regimens for children

| First line | Second line |
|--|--|
| ZDV + 3TC + NVP If < 10 kg, ZDV + 3TC + NFV | ddI + D4T + NFV ABC + ddI + NVP (if < 10 kg) ABC + ddI + EFV (if 10–15 kg) D4T + ddI + NFV (if > 15 kg) |
| If ≥ 10 kg, ZDV + 3TC + EFV | ABC + ddI + NFV (if < 15 kg) D4T + ddI + NFV (if ≥ 15 kg) |
| If < 15 kg, ZDV + 3TC + NFV | ABC + ddI + NVP (if < 10 kg) ABC + ddI + EFV (if 10–15 kg) D4T + ddI + EFV (if > 15 kg) |
| If ≥ 15 kg, D4T + 3TC + NVP | ZDV + ddI + NFV |

MONITORING OF MTCT-PLUS PARTICIPANTS

The people participating in MTCT-Plus are carefully monitored clinically and in the laboratory. Standardized protocols have been developed with the understanding that, in some settings, clinical officers rather than physicians or nurses may provide HIV care. Algorithms appropriate for these officers have been developed, although more individualized care may be provided at sites with access to greater clinical expertise.

Clinical visit schedules are dictated by disease stage, and emphasis is placed on retaining participants in care even if they are asymptomatic. At each clinical visit, a symptom checklist is used (Fig. 3), and participants undergo targeted physical examination if indicated. Symptoms are evaluated, laboratory tests are ordered if appropriate and the person is restaged at the end of each visit. At each visit, eligibility for prophylaxis and antiretroviral therapy is reassessed.

In the absence of evidence to guide laboratory protocols, the question of how much laboratory monitoring to include in the essential package was debated at length. Priorities included not only safety for the people living with HIV/AIDS but the need to demonstrate programme effectiveness and to create a model of care that could be generalized and used by sites without access to sophisticated laboratory infrastructure. In the end, the decision was made to use laboratory monitoring guidelines during the first year of the MTCT-Plus Initiative and to reassess these as it developed. These preliminary guidelines include:

- immune monitoring via CD4 count every 6 months for all participants in MTCT-Plus;
- baseline laboratory assessment for participants initiating antiretroviral therapy: haematological assessment, assessment of liver function and assessment of kidney function;
- virological testing of infants to determine HIV status; and
- additional testing as needed only: to be dictated by clinical symptoms or signs.

Fig. 3. Sample symptom checklist for MTCT-Plus sites

| Sign or Symptom | Yes | Sign or Symptom | Yes |
|--|-----------------------|--------------------|-----------------------|
| Cough | <input type="radio"/> | Pain – Abdominal | <input type="radio"/> |
| Depression | <input type="radio"/> | Pain – Muscles | <input type="radio"/> |
| Diarrhea | <input type="radio"/> | Pain – Legs/Feet | <input type="radio"/> |
| Difficulty Breathing | <input type="radio"/> | Poor appetite | <input type="radio"/> |
| Fatigue | <input type="radio"/> | Rash | <input type="radio"/> |
| Fever | <input type="radio"/> | Trush | <input type="radio"/> |
| Headache | <input type="radio"/> | Weakness | <input type="radio"/> |
| Memory problems | <input type="radio"/> | Weight gain | <input type="radio"/> |
| Nausea and/or vomiting | <input type="radio"/> | Weight loss | <input type="radio"/> |
| New visual problems | <input type="radio"/> | Other 1 (specify): | <input type="radio"/> |
| Night sweats | <input type="radio"/> | Other 2 (specify): | <input type="radio"/> |
| Numbness or tingling in legs and/or feet | <input type="radio"/> | Other 3 (specify): | <input type="radio"/> |

HUMAN RESOURCES

One of the initial working groups assembled in 2001 was dedicated to human resources and HIV/AIDS care. Building on this early work, an MTCT-Plus Training Working Group was established in mid-2002. Clinicians and educators worked with sites to develop a training plan for the Initiative and settled on a competency-based model. A train-the-trainer model was considered but rejected based on feedback from sites. The decision was made to conduct on-site multidisciplinary training, taking into account local experience and expertise.

MTCT-Plus developed a detailed set of competencies expected for each type of provider – clinicians (physicians, nurses and clinical officers), providers of supportive services (counsellors, educators and psychosocial care providers) and administrators (programme managers, clinic managers and pharmacists). Competencies were also identified for each type of visit – screening, enrolment, follow-up, laboratory visit, pharmacy visit etc. MTCT-Plus competencies, sub-competencies and learning objectives are available by contacting MTCT-Plus at mtctplus@columbia.edu.

These competencies and learning objectives informed the development of a series of foundation training modules. Rather than merely updating information, the MTCT-Plus training programmes focused on teaching the skills needed to implement the protocols outlined in the clinical manual. Emphasizing the utility of multidisciplinary care, interdisciplinary teams were trained together, promoting the value and contributions of each team member. Training modules include detailed slide sets, as well as case studies and interactive classroom exercises (Box 3).

PROCUREMENT OF MEDICATION AND SUPPLIES

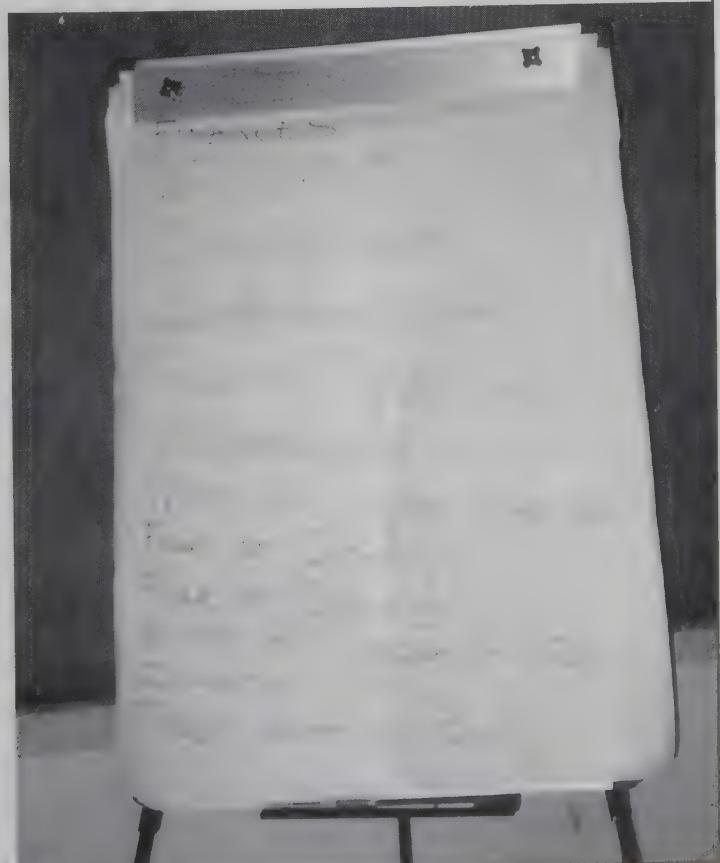
In partnership with the United Nations Children's Fund (UNICEF), MTCT-Plus has established a centralized procurement system for programme-specific medication and supplies. These include antiretroviral agents, cotrimoxazole, dapsone, isoniazid, multivitamins and items such as tuberculin skin testing kits and pill boxes. These medicines and supplies are delivered to the sites directly. Central procurement is an efficient system that allows access to the least costly sources of medicines. In partnership with John Snow Inc., local pharmacy management is assessed and enhanced where necessary. In addition, MTCT-Plus helps sites in developing a secure medication management system and in accurately forecasting the supplies needed.

Box 3. MTCT-Plus foundation training modules

- Coordination of family care
- Adherence to care
- Adherence to treatment
- Adherence in children
- Nutritional assessment and support
- Psychosocial assessment and support
- Care of adults (includes clinical staging and prophylaxis)
- Antiretroviral therapy for adults
- Care of children (includes clinical staging and prophylaxis)
- Antiretroviral therapy for children

Additional modules

- Education
- Diagnosis of HIV in infants
- Antiretroviral therapy in pregnant women
- Treatment of HIV/tuberculosis co-infection
- Children's growth and nutrition
- Stigma
- Prevention of HIV transmission



MTCT-Plus training teams visited 10 sites in early 2003 (Fig. 4). The visits ranged from 3 to 7 days. The teams were interdisciplinary, including nurses, physicians, counsellors and educators. Assessment includes immediate questionnaire-based feedback from trainees as well as ongoing competency-based evaluation performed at quarterly site visits. Follow-up training will be provided at least annually, and this training will be assessed through written pre- and post-testing. The frequency of training will be based on site needs and the components of the training will be developed in collaboration with the sites.

Fig. 4. From an MTCT-Plus training programme, Kigali, Rwanda, February 2003



COMMUNITY INVOLVEMENT

Linkage to local community resources – such as nongovernmental organizations, community-based organizations and traditional healers – is a hallmark of the MTCT-Plus Initiative. The complexity of HIV/AIDS care demands a multisectoral approach, and each MTCT-Plus site is strongly encouraged to develop a formal inventory of local assets. In addition, the Initiative supports outreach workers, peer educators and support groups for people living with HIV/AIDS, all with strong links to the community. Many MTCT-Plus sites are also enriched by community advisory boards.

The MTCT-Plus Initiative has also established the African Women's Leadership Group to guide and support its efforts (Fig. 5). The Group consists of several eminent women including parliamentarians, leaders of community-based organizations and women actively involved in HIV-related

efforts within their communities. The Group is committed to providing support to the MTCT-Plus sites in their communities, to overcoming the stigma faced by women with HIV disease and to enhancing the rights of women in general. Graça Machel, the former Minister for Education of Mozambique, chairs the Group.

Fig. 5. African Women's Leadership Group, Johannesburg, February 2003



ADHERENCE SUPPORT

The MTCT-Plus Initiative was designed with acute awareness that adherence to treatment among participants is key to the success of individuals and the Initiative as a whole. Efforts have focused on adherence to care and adherence to treatment.

Adherence to care

The introduction of a continuity care model into settings in which episodic care is the norm poses specific challenges to the health care system. At some sites, this is the first time an appointment system has been used. At others, medical record-keeping is skeletal and on-site medical records a novelty. The care of mothers and the care of children are rarely coordinated. Providers are not always motivated to encourage the attendance of asymptomatic participants, and the participants are accustomed to coming to clinic only when ill.

The MTCT-Plus Secretariat has worked with each site to develop and enhance systems of care, supporting additional staff and training, peer support, education of participants and community outreach. MTCT-Plus forms have been designed so that they can be used as a medical record. MTCT-Plus funds can be used to expand clinic hours and/or to pay for transporting participants. At some sites, the wait-

ing area has been expanded. At others, additional outreach workers have been hired to follow up on missed appointments. Sites have purchased locked filing cabinets to secure records, developed education materials for participants and instituted both paper-based and computer-based appointment systems.

At all sites, the MTCT-Plus Initiative has stressed the importance of regular interdisciplinary team meetings to share information, review plans and coordinate care. Providers are encouraged to consider barriers to adherence to care (Can the person living with HIV/AIDS afford transport costs? Does she have someone to watch her children? Does she have family support?) and to develop strategies to support adherence where possible.

Adherence to treatment

Adherence to medication is the cornerstone of successful HIV/AIDS care and the focus of MTCT-Plus training. Before antiretroviral therapy is initiated, sites formally assess adherence and barriers. Clinic attendance is reviewed. Adherence to preventive therapy is assessed. Disclosure is encouraged – at many sites, a medication «buddy» is required. Education of participants focuses on adherence to medication. Support groups and peer educators are available and, at some sites, mandatory.

Since the first months of antiretroviral therapy are critically important, the people in therapy are followed very closely during this period. Participants usually return to clinic on a weekly basis for at least 2 months after antiretroviral therapy is initiated. One site has instituted modified directly observed therapy: one daily visit to clinic five times per week. One site will alternate twice-weekly home visits with twice-weekly clinic visits. This additional surveillance is intended to reinforce adherence lessons, provide ongoing support and enable participants to access care easily if they experience side-effects from medication.

Although personal support and education of participants are key to supporting adherence, the MTCT-Plus Initiative also supplies practical adherence tools such as pill boxes, hand-outs, and medication blister packs.

PSYCHOSOCIAL SUPPORT AND OUTREACH ACTIVITIES

HIV/AIDS care cannot be delivered effectively in a vacuum. More is needed than drugs, and a programme that is not responsive to the real-world environment in which people with HIV/AIDS live is unlikely to be successful. Supportive services – education, counselling and empowerment – are an integral part of the MTCT-Plus Initiative. The multidiscipli-

nary team includes counsellors and social workers, support groups and peer educators tailored to site needs and environments. At many sites, community workers provide home visits. One site plans to initiate a dialogue with local traditional healers. Another has initiated modified directly observed therapy supervised by community activists for people on antiretroviral medication. At all sites, linkage to community resources is a priority.

DATA MANAGEMENT

The MTCT-Plus Data Working Group spent months developing simple forms that could collect key information and guide the management of participants (Box 4, Fig. 6). The objective was to assist sites in creating and maintaining the strong medical records required for continuity of care, to enable MTCT-Plus to provide feedback to sites to enable ongoing improvement of quality, to facilitate cross-site assessment and sharing of lessons learned and to determine the impact of the MTCT-Plus Initiative.

The forms, created in partnership with John Snow Inc., are intended to assist clinicians by guiding them through the MTCT-Plus care algorithms. They use checkboxes and simple skip patterns and highlight therapeutic decisions such as initiation of prophylaxis for opportunistic infections or antiretroviral therapy. These duplicate forms may be used as a chart; one copy is sent to the Data Management Center and one is kept as the medical record. Some sites use their own forms and enter key data directly on site. The Data Management Center will generate regular reports for each site, including participant enrolment and follow-up statistics, key clinical parameters for each participant and reminders to sites of anticipated participant visits.

Box 4. MTCT-Plus forms

- Intake form
- Locator form
- Enrolment form (adult, infant or child)
- Follow-up form (adult, infant or child)
- Laboratory result form
- Non-clinical encounter form
- Infant HIV diagnosis form
- Programme discontinuation form

Fig. 6. Follow-up form for adults

What tests will be ordered for the patient?

Fill in «o» for all that apply

- None
- Complete Blood Count
- CD4 Count Assay
- ALT (Alanine Aminotransferase)
- ALT (Aspartate Aminotransferase)
- Creatinine
- Electrolytes
- Tuberculin skin test
- Sputum for AFB
- Pregnancy test
- Radiology Test (specify):
- Other (specify):

What referrals will be made for the patient?

Fill in «o» for all that apply

- None
- Family planning services
- Nutritional support
- In-patient care / Hospitalization
- Social support services
- TB treatment / DOT program
- Adherence counseling
- Mental health services
- Psychosocial counseling
- Other referral:

When is the patients next appointment?

Fill in appropriate «o»

- 1 week
- 1 month
- 3 month
- 6 month
- Other (specify):

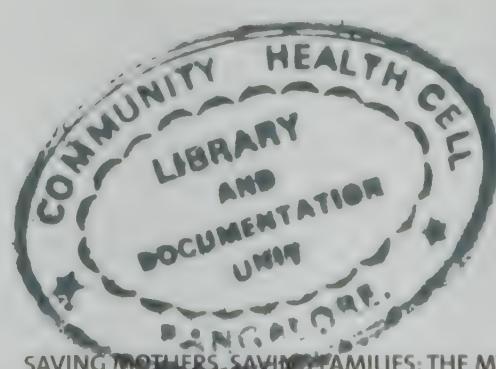
Appointment date:

date month year

EVALUATION

Enrolment in the MTCT-Plus Initiative began in February 2003. By the end of June 2003, 572 people had been enrolled, including women as well as their partners and children. Women have been enrolled either during their pregnancy, while in antenatal care or after birth.

The MTCT-Plus Evaluation Working Group has identified specific indicators that will be assessed regularly to help in assessing sites and in cross-site evaluation. In addition, broad outcome measures have been developed to assess programmatic impact. Indicators include the number of participants enrolled, the retention of participants in care, hospitalization rates, rates of clinical complications and mortality rates. These parameters can be assessed in MTCT-Plus as a whole as well as across sites. Information and feedback is provided to the sites to facilitate problem-solving. In addition, cross-site data is used to promote the sharing of successful models between sites.



FUTURE DIRECTIONS

The lessons learned from the MTCT-Plus Initiative should be immensely helpful to other HIV/AIDS care and treatment programmes. By demonstrating the effectiveness of this comprehensive approach to care and of the specific treatment algorithms, the Initiative aims to catalyse the expansion of HIV/AIDS care in resource-poor settings. MTCT-Plus provides a unique model and an inspiration to donors and programmers alike. It can also contribute to the diversity of HIV care and treatment models that will be necessary in the process of scale-up of HIV care and treatment in resource-limited settings. As additional public and private funds become available, the Initiative can provide an example of sustainable and effective HIV/AIDS care.

As the MTCT-Plus Initiative expands, new sites will be added and the number of participants at each of the initial sites will grow. The experience at these sites will guide future expansion and allow for more efficient and effective development of sites. Future directions for MTCT-Plus include increasing the variety of clinical settings, reducing the complexity of laboratory monitoring, increasing the diversity of clinical providers and sharing experiences across and between sites.

Increasing the variety of clinical settings

At present, most MTCT-Plus sites are in urban or periurban areas. As the Initiative expands, attempts will be made to add rural sites and to further increase the diversity of health care settings in which MTCT-Plus programmes will be established.

Reducing the complexity of laboratory monitoring

Current MTCT-Plus algorithms use CD4 counts for monitoring HIV disease stage and the response to therapy. In addition, virological tests are used for diagnosing HIV in infants. Although many sites will continue to use these protocols, we anticipate that some will provide HIV care and treatment with less sophisticated laboratory monitoring, such as the use of total lymphocyte counts for staging of HIV disease.

Increasing the diversity of clinical providers

Although physicians are available at each of the initial MTCT-Plus sites, some utilize clinical officers as the mainstay of their HIV care workforce. Future endeavours will attempt to expand the roles of nurses and clinical officers at MTCT-Plus sites.

Sharing experiences across and between sites

Each of the Initiative sites is gaining a wealth of experience. Opportunities for sharing these experiences will be very important. In addition to an annual MTCT-Plus team meeting in which lessons learned are shared between sites, as new sites are added, existing programmes will be used as centres of clinical excellence, enhancing training and providing support to regional sites. In addition, links between specific types of providers will be encouraged. For example, establishing an MTCT-Plus nurses' group may allow specific experiences to be shared and the role of nurses in HIV care and treatment programmes to be expanded.

CONCLUSION

The MTCT-Plus Initiative focuses on providing HIV care and treatment to a particular group of people living with HIV/AIDS. It aims to give the enrolled families comprehensive HIV care through multidisciplinary teams. The Initiative focuses not only on clinical services but on including all the other supportive services needed by the participants. The resources MTCT-Plus provides in building the human and resource infrastructure at the various sites will help in building other HIV care and treatment programmes in these communities. Thus, resources from other programmes can be rapidly used to build such programmes and to provide care and treatment to the many people who need it in resource-limited settings.

ADDITIONAL TOOLS

MTCT-Plus Patient Data Manual. Version 1.1. January 2003.

This manual describes the patient data collection systems and procedures for the MTCT-Plus Initiative. For information on this manual, contact the MTCT Plus secretariat at mtctplus@columbia.edu. (The MTCT-Plus Initiative, Mailman School of Public Health, Columbia University, 722 West 168th Street, New York, NY 10032, USA. Tel. : +1 212 342 0505; fax: +1 212 342 1824), or the data management center staff at Mtctplusdmc@jsi.com (44 Farnsworth Street, Boston, MA 02210-1211, USA. Tel.: +1 617 482 9485, fax: +1 617 482 0617).

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